

FREQUENTLY ASKED QUESTIONS

Who can join this study?

People diagnosed with cancer that are currently receiving chemotherapy and experiencing cognitive problems.

How long will the visits take?

The two office visits will take approximately 2 ½ to 3 hours each.

How long will I be in the study?

Your participation will last 6-7 weeks.

How many people will participate?

116 patients will be enrolled.

Is there any cost to participating?

There will be no cost to you.

Will I be paid for participating?

You will be paid up to \$100 for taking part in this study. All participants will receive the contents of the exercise kit and a wrist-worn activity tracker to keep.

What risks are involved?

There are little to no risks being involved in this study. Specifics will be discussed if you enroll.

Are there any benefits to participating?

You may or may not benefit from this study.

Can I leave the study?

You may discontinue participation at any time without risking loss of present or future care.

If you have noticed any changes in your cognitive functioning and would like more information, please contact:

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The Department of Surgery-Cancer Control would like to thank you for considering participating in this project.



WILMOT
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PATIENT INFORMATION:

A Phase II Study of the Effects of Physical Activity and Low Dose Ibuprofen on Cognitive Function in Cancer Patients Undergoing Chemotherapy



This research is being conducted by the University of Rochester Medical Center Department of Surgery-Cancer Control

RSRB-University of Rochester-Approval
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Expires: 6/16/2019

URCC CCPL
NCORP Research Base Cancer Control and Psychoneuroimmunology Lab

COGNITIVE DIFFICULTIES IN CANCER PATIENTS

Many cancer patients report mild to moderate cancer-related cognitive difficulties (such as problems remembering things, multi-tasking, or concentrating) during and following treatment of their cancer and currently, we do not have a treatment for these problems.

We believe that cognitive difficulties related to cancer and chemotherapy treatments may be related to increased inflammation in the body. This has been associated with cognitive difficulties in other diseases and the same may be true for cancer and cognition. Both exercise and ibuprofen have also been associated with reducing levels of inflammation. In this study, researchers will investigate how exercise and ibuprofen influence levels of inflammatory markers in your blood during your chemotherapy.

The researchers leading this study are also interested in how cognitive difficulties may relate to other symptoms you may or may not develop such as fatigue, sleep problems, anxiety, and how exercise and ibuprofen may affect these symptoms.



STUDY GROUPS

There are 4 different treatment combinations and you will be placed into one of these groups at random using a computer:

Group 1	Placebo 200 mg twice daily
Group 2	Placebo 200 mg twice daily + Exercise program
Group 3	Ibuprofen 200mg twice daily
Group 4	Ibuprofen 200mg twice daily + Exercise program

Exercise for Cancer Patients (EXCAP[®])



The exercise program being studied in this research consists of both aerobic and resistance training components using a pedometer and resistance bands each day.

Ibuprofen



The anti-inflammatory being studied in this research is a low dose over the counter ibuprofen.

WHAT TO EXPECT

If you agree to participate, your standard of care will not change.

You will be asked to complete the following at the beginning and the end of the study:

- Filling out questionnaires
- Completing computerized and paper based cognitive tests
- Fitness evaluations
 - Bioelectrical impedance analysis (BIA) to measure lean body mass
 - Cardiovascular treadmill test
 - Resting metabolic testing
 - 2 tests for muscular strength
- Wearing a pedometer (3 days)
- A fasting blood draw (less than 2 tablespoons)

You will be asked to complete the following during the study:

- Brief daily diary about your symptoms
- A study coordinator will contact you once a week for updates
- Take study medication twice a day
- Exercise program (If assigned to Group 2 or 4)